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# **Dräger** medical

A Dräger and Siemens Company

# Field Service Procedure

Part Number: SP00225 Rev: M

Date: 17 June 2004 © 2004 Draeger Medical, Inc.

Fabius GS® PMS Procedure

FABIUS GS PMS PROCEDURE

# 7.0 PMS PROCEDURE, FABIUS GS

The procedures in this section shall be performed in their entirety each time a component is removed, replaced, calibrated, adjusted and during all scheduled Periodic Manufacturer's Service (PMS) visits. A PMS Checklist form, available from DrägerService, shall be completed by the Technical Service Representative (TSR) each time a PMS is performed. Steps in the procedure marked with ( $\checkmark$ ) require a response at the corresponding line on the checklist form. Space is also provided on the PMS checklist form to record the results of a vapor concentration test. Contact DrägerService for vapor concentration verification procedures.

**NOTE:** Verify the dates on test equipment calibration labels. DO NOT USE any test equipment having an expired calibration date. Notify your supervisor immediately if any equipment is found to be out of calibration.

In the space provided at the bottom of the PMS checklist form, record the Model and ID number of all calibrated test equipment used. Also record the calibration due dates. Examples are: multimeter, digital pressure meter, Riken gas analyzer, safety analyzer, volumeter, trace gas analyzer, simulators.

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# **Test Equipment Required:**

- -- Multi-Meter (Fluke or equivalent)
- -- Electrical Safety Analyzer (Biotek 501 Pro or equivalent)
- -- Test Pressure Gauge, P/N 4114807 or equivalent
- -- Fresh Gas Test connector, P/N 4117361 or equivalent
- -- Fresh Gas Leak Test Device, P/N 4113119 or equivalent
- -- Test Cap, P/N M33972 or equivalent: two are required
- -- Adapter Assembly, Test Terminal, P/N 4104389 or equivalent: two are required
- -- Flowmeter Test Stand (0-250 cc), P/N S000081 or equivalent
- -- Breathing System Leak Test Device, P/N S010159 or equivalent
- -- Baromed Pressure Test Fixture or equivalent
- -- Test Minute Volume Meter, P/N 2212300 or equivalent
- -- Digital Pressure Manometer (SenSym PDM 200CD or equivalent)
- -- Riken Gas Indicator, Model 18H, or 1802D or equivalent
- -- Hose Asm, vapor testing (for use w/Riken gas indicator), 4117905
- -- Stop Watch
- -- Siemens Test Lung, P/N 8401892
- -- Rubber Plug, P/N 7901297
- -- Tube, Corrugated, 22 mm x 12 in. long, P/N 9995112

#### Accessories:

- -- T-connector, P/N M32803
- -- Washer, M4 white (3x) M31602 (for T-connector above)
- -- Fitting, Str 1/4 tube x 1/8 NPT, P/N 4109318
- -- Fitting, Str 0.130 ID hose x 1/8 MPT, P/N 4102963

# Materials Required:

- -- Breathing Bag, 3 liter, P/N 9995330 or equivalent
- -- DI-Wacker Silicon Rubber, P/N 1202537
- -- Loctite #222, Purple, P/N 4118558-001
- -- Loctite #271, Red, P/N 4118558-003
- -- Loctite #425. Blue, P/N 4118558-008

#### Repair Tools:

- -- Plastic Jaw Pliers, P/N 7910296
- -- Nut Driver (modified), P/N 4117530
- -- Nut Driver (two-hole spanner). P/N 7910305
- -- Cable Assembly, flash load RAM, P/N 4117459
- -- Nut Driver, 3/8 in.
- -- Cable Assembly, Vitalink, P/N 4110328
- -- Hose cutter, P/N 7900894
- -- Spanner Wrench, Insert/Extraction, P/N 4118165
- -- Scalpel P/N 4118169
- -- Spanner Wrench, Bag Arm Extension, P/N 4117773
- -- Pozi Drive Set
- -- Wrench, Caster, P/N S010055

Test equipment illustrations are shown on following pages.

# **Fabius GS Parts Replacement Schedule:**

Quantity	Description	Part Number	Alternate Part Number
	As Required		
1	Flow Sensor (5 pack)	8403735	
1	O2 Sensor	6850645	
2	O-ring, Vent Hose	2M08777	
2	Valve Disc	2123249 or M23225	
1	Hose asm, PEEP/Pmax - APL Bypass	4117027	
1	Hose, Pressure	1190520	
1	Filter, AGS	M33294	
Annu	ally: Fabius GS/Tiro 1 year kit	4117360-001	4199912
2	Filter, Pressure & Pneumatic asm	8402868	
1	Diaphragm, Patient	2600650	
4	O-ring, Vapor	4115864	
1	O-ring, for Diaphragm (piston)	8604831	
Every 3	3 Years: Fabius GS/Tiro 3 year kit	4117360-002	4199911
1	Diaphragm, Piston	2600651	
2	Battery, 12V Rechargeable	4114229	
1	Canister Assembly	M29320	
1	Lip Seal	M30455	
1	Packing Ring	M30456	
1	PM Kit; 1 Year	4117360-001	4199912

# Disposal of used batteries and O2 Sensors:

- Batteries must be disposed of in conformity with local waste disposal regulations.
- Expired O2 sensors can be returned to:

Dräger Medical AG & Co. KGaA

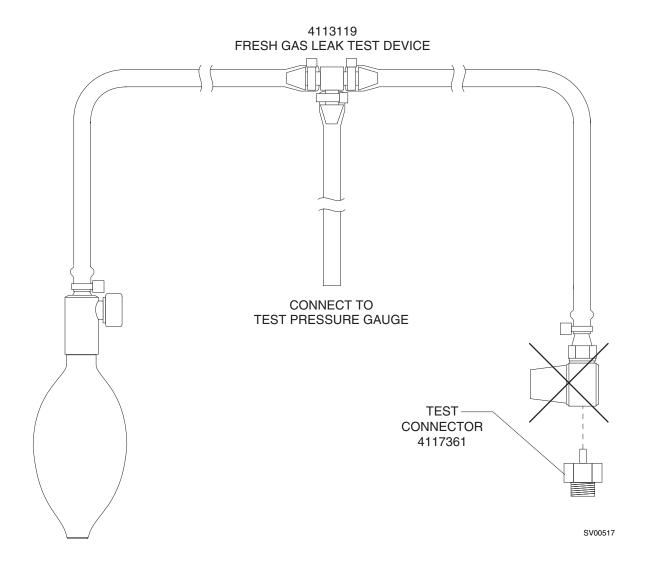
Moislinger Allee 53-55

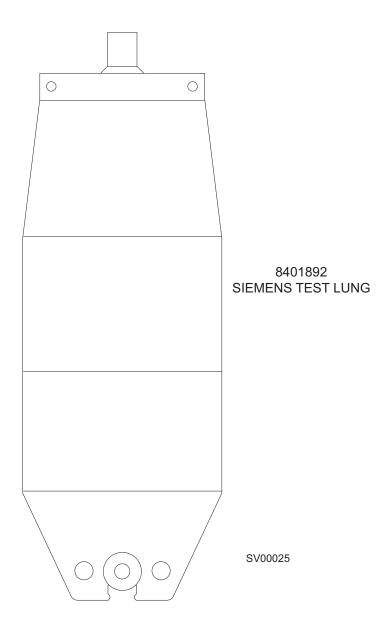
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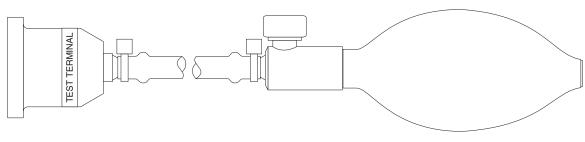
23542 Lübeck

Germany

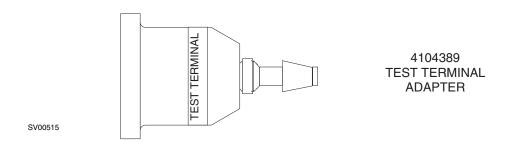
- Do not open forcibly: danger of chemical burns.
- Do not incinerate: danger of explosion.



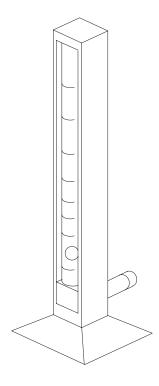




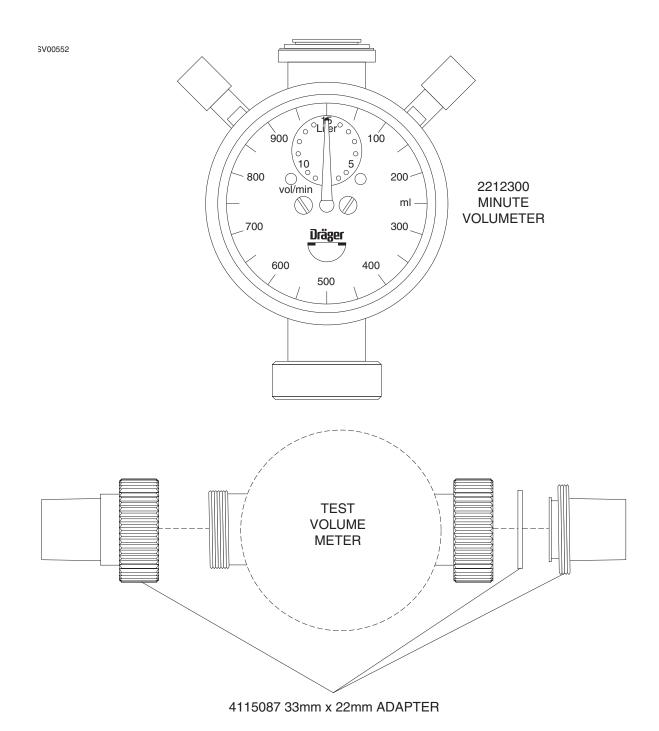
S010159 BREATHING SYSTEM LEAK TEST DEVICE



SV00559



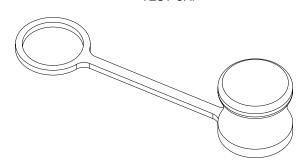
S000081 FLOW METER TEST STAND 0-250cc/MIN



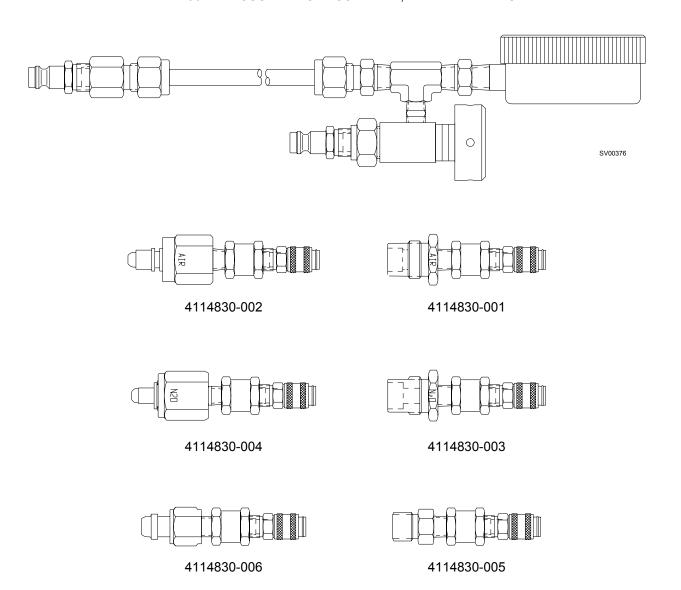
SV00516

PMS PROCEDURE (continued)





# 4114807 PRESSURE TEST ASSEMBLY, WITH ADAPTERS



**PMS PROCEDURE (continued)** 

#### Periodic Manufacturer's Certification General Instructions

The purpose of these procedures is to provide detailed instructions for performing a Periodic Manufacturer's Certification (PMC) inspection on the Fabius GS anesthesia machines.

A PMC consists of a complete Periodic Manufacturer's Service procedure and a certification level inspection based on Draeger Medical, Inc. Recommendations and equipment performance. Additional inspections are also performed to ensure proper product labeling.

Several additional documents have been created to assist the technician through the process. Following is a brief description of the purpose of each document.

#### Field Service Procedure:

Periodic Manufacturer's Certification Forms - Part Number SP00175.

This procedure illustrates the sample checklists with typical periodic maintenance items filled in, including vapor concentration verification tests, parts replaced, general comments and certification levels. Also included are sample PMC labels marked to show several levels of certifications. An excerpt from Draeger Medical, Inc.'s *Anesthesia System Risk Analysis and Risk Reduction* is included, and also a sample of an Executive Summary to be furnished to the hospital's Risk Manager or Chief of Anesthesia.

#### Field Service Procedure:

NAD Recommendation Guidelines Index Anesthesia Systems - Part Number S010250. This Guideline was created to provide an assessment of each machine's certification. It contains various comprehensive overviews of possible equipment conditions and their associated certification levels.

The first list in the Recommendation Guidelines is a reference chart for machine certification based on equipment status. The second is an abbreviated summary of all NAD Recommendations and Failure Codes including the Condition Number, Equipment Condition, Recommended Corrections, Certification Code, and Tests Affected when applicable.

There is also a matrix classified as "Failure Codes" which identifies the correct manner in which to document equipment tests that fail, or were unable to be performed due to circumstances beyond the control of the service technician performing the inspection. (Ex: Air cylinder supply is unavailable to perform Air High Pressure Leak test.) The Failure Codes section also indicates suggested resolution of the situation. Failure Code numbers begin at 34 and use the same certification levels strategy, and carry the same weight as NAD Recommendation equipment condition codes.

The next section of the guideline lists all NAD Recommendations identified at a machine's major assembly level. This section is divided into subsections titled: "Anesthesia System", "Vaporizers", "Absorber System", "Ventilator" and "Scavenger System". The final matrix is the most comprehensive index sorted by machine model and includes Equipment Condition, Certification Code, and NAD Recommendations. It also specifies any suggested upgrade path including ordering information that should be taken such as installing a Bellows with Pressure Limit Control 4109664-S01 Kit, after market modification kit to a machine not equipped with pressure limit control.

The letters A, B, C, D and the Roman Numerals I, II are used as codes in the individual matrix for each model of anesthesia machine. The letters A, B, C, and D are used in descending order to indicate the certification level of the equipment. They are as follows:

- A = Certified
- B = Certified with Recommendations
- C = Conditionally Certified
- D = No Certification

Roman Numerals I and II do not affect the certification level but rather are provided to give further instructions to the end user as follows:

- I = The system in its present configuration shall only be used with a CO2 monitor incorporating an apnea warning. The operator of the system is advised to frequently scan the CO2 readings and alarm thresholds.
- II = The present configuration of equipment requires that the unit operate at all times with an oxygen analyzer that includes a low oxygen warning. The operator of the system is advised to frequently scan the oxygen readings and alarm limits.

Following is an explanation of machine certification levels:

**Certified-** No recommendations apply to machine being inspected. (Only item number 33 - "No Recommendations" shall apply for this certification level.)

**Certified with Recommendations-** A numbered recommendation with a code of B applies to the machine being examined.

**Conditionally Certified-** A numbered recommendation with a code of BC, BCI or BCII applies to the machine being examined.

**No Certification-** A numbered recommendation with a code of D applies to the machine being examined.

When multiple recommendations apply, use the above list in descending order from bottom to top. For example, "No Certification would take precedence over "Conditionally Certified" and "Certified with Recommendations". "Conditionally Certified" would take precedence over "Certified with Recommendations".

For example:

A **Narkomed Standard** or **Compact** could have recommendation numbers 10, 11 and 15 apply.

- 10 Breathing pressure monitor is not interfaced with anesthesia machine system power switch or ventilator. Code is B.
- 11 Ventilator is equipped with descending bellows and lacks CO2 monitoring. Code is D1.
- 15 Vaporizer mounting using a vaporizer selection valve. Code is B.

The correct certification for this machine is D, which means "NO CERTIFICATION", and additional recommendation I applies.

A **Narkomed AMIII** or **Narkomed II** could have recommendations 6 apply, and failure code 46.2.

6 - Oxygen ratio monitor instead of oxygen ratio monitor controller. Code D II. 46.2 - O2 analyzer malfunction. Code D.

Correct certification for this machine is D, which means "NO CERTIFICATION".

A Narkomed 2A could have recommendation numbers 12, 14 and 27 apply.

- 12 No integrated exhaled CO2 monitor with user adjustable alarm limits. Code D1.
- 14 CO2/Agent monitor exhaust port is not properly connected to waste gas disposal system. Code B.
- 27 Ventilator bellows assembly has a PEEP valve assembly. Code B.

Correct certification for this machine is D1, which means "NO CERTIFICATION", and additional recommendation I applies.

A Narkomed 3 could have recommendation number 21 and failure code 61.1 apply.

- 21 No ventilator pressure limit control. Code is B.
- 61.1 Enflurane agent is unavailable to test. Code is BC.

Correct certification for this machine is BC, which means CONDITIONALLY CERTIFIED WITH RECOMMENDATIONS.

A Narkomed 4 could have recommendation numbers 14 and 21 apply.

- 14 CO2/Agent monitor exhaust port is not properly connected to the waste gas scavenger. Code B.
- 21 No ventilator pressure limit control. Code B.

The correct certification for this machine is B, which means "CERTIFIED WITH RECOMMENDATIONS".

A Narkomed 2B, 2C or GS could have recommendation 30 apply.

30 - Anesthesia machine is equipped with inhalation anesthesia vaporizers without an agent analyzer in the breathing system. Code B.

The correct certification for this machine is B, which means "CERTIFIED WITH RECOMMENDATIONS".

A **Narkomed 6000** could have no NAD recommendations or failure codes apply. The correct certification level for this machine is Code A, "CERTIFIED".

Code D, which means "NO CERTIFICATION", also means the machine shall not receive a Periodic Manufacturer's Certification label. The machine shall also receive a "WARNING - This System is Not Certified" label, P/N 4114857. This label shall be placed at a prominent location on the right side of the machine after all other previous PM and "Vigilance Audit® Validation" labels have been removed.

# PM Certification Procedure for Fabius GS Anesthesia System

- 1. Use the PM Certification form P/N 4117715 for the Fabius GS Anesthesia System.
- 2. Completely fill in the header information.
- 3. Perform the vapor concentration test on all Dräger vapor vaporizers every six months in accordance with SP00073 at a six month maximum interval. Perform the vaporizer concentration test on all Desflurane vaporizers in accordance with SP00091 for fixed mount vaporizers and SP00189 for user removable D-tec vaporizers at a six month maximum interval. For every vaporizer tested, fill out a "VAPOR VAPORIZER CALIBRATION CHECK" label (part # S010016). Information on this label shall include your signature, type of agent, date tested, test results @ 1%, 2.5%, 4% for H, E, I, or S vaporizers, or @ 4%, 6%, 10%, 12%, 16% for Desflurane vaporizers, and a PASS or FAIL indication. This label shall be attached to the upper right side of the vaporizer. If vaporizer fails the concentration verification, internal leak, or exclusion system tests, check "NO" in the "RECOMMENDED FOR USE" section on the PM Certification form.

Place a "<u>CAUTION</u> DO NOT USE" label (part # 4114327) on the vaporizer, and issue a departmental alert. The TSR shall also seek permission from the equipment operator to remove the failed vaporizer from the machine and install a replacement vaporizer or an adapter block onto the mount. All nonfunctional Dräger vaporizers must be removed from service for machine to receive certification.

4. Proceed with PM Certification in accordance with Section 7. If any tests fail refer to the "Failure Codes" listing in NAD Recommendations Guidelines Index, P/N S010250, to determine correct certification level starting point. Failure codes shall be documented on the "RECOMMENDATIONS / GENERAL COMMENTS" section of the PM Certification form and on the Executive Summary if applicable. If a test fails that has not been identified by the "Failure Codes" list, consult with Draeger Medical, Inc. to assess the proper certification level.

# PM Certification Procedure for Fabius GS Anesthesia System

- 5. Based on the "EQUIPMENT CONDITION" inspect the machine for any "NAD RECOMMENDATIONS" that would apply. Use the Fabius GS section of the "NAD RECOMMENDATION GUIDELINES INDEX", P/N S010250. Note all applicable NAD recommendations on the Executive Summary. NOTE: If using a carbon form, indicate the Equipment Condition number and to see reverse side under "RECOMMENDATIONS / GENERAL COMMENTS" section of the form.
- 6. Determine the correct certification level of the machine based on the combined lowest common denominator of "Equipment Conditions" and "Failure Codes". If the machine is at least conditionally certified, fill out the "PM CERTIFICATION" label. Check the box(s) on the validation label where appropriate. Write the month and year, (six months from date of PM Certification) next to "NEXT VISIT DUE:" If certification level is "D", machine shall not receive a "PM CERTIFICATION" label. Any machine not receiving a PM Certification label shall receive a "WARNING NOT CERTIFIED" label. This label shall be placed at a prominent location on the left side of the machine after all other previous PMS and Vigilance Audit Validation labels have been removed.
- 7. In the "CERTIFICATION LEVEL" section of the PM Certification form, record the last visit certification level, the current certification level and the next visit due month and year, (six months from date of PM Certification) in the spaces provided.
- 8. If applicable, remove the previous PM CERTIFICATION VALIDATION label and attach the new label in a prominent location on the rear of the anesthesia machine.
- 9. Check the appropriate boxes on the "PM CERTIFICATION NOTICE" label, (part # S010011). If the machine is not certified, the last box of this notice label shall be checked. Attach this notice to the flow shield of the anesthesia machine.
- 10. Have the customer sign each PM Certification form or the Executive Summary, and review the equipment conditions and recommendations with the customer.
- 11. Return the top copy to Draeger Medical, Inc. Service Department, keep middle copy for service organization records, give bottom copy to customer.

**NOTE:** The following procedure will require making adjustments and calibrations with the possibility of removal of accessories and/or additional monitoring equipment. Therefore, take note of these devices for reconfiguration and/or reinstallation after the PMS procedure is complete.

### 7.1 Electrical Safety

- (✓) 7.1.1 Protective Ground Continuity
  - 7.1.1.1 Turn the System Power switch to STANDBY.

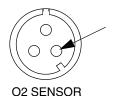
Plug the unit into the safety analyzer, and plug the power cord of the safety analyzer into an AC receptacle. Turn analyzer to ON position.

- **NOTE:** The BIOTECH 501 PRO will automatically test the source outlet for open ground (or ground resistance of 31  $\Omega$  or higher), reverse polarity, open neutral and open line. (The latter two conditions will prevent the analyzer from powering up.)
- 7.1.1.2 Set the safety analyzer function switch to the GROUND WIRE RESISTANCE position. Attach the test lead to the SINGLE LEAD connector of the analyzer. Connect the other end of the red test lead to the ground socket of the front panel outlet on the safety analyzer. Verify a displayed resistance of  $0.000~\Omega$  or, if necessary, press the CALIBRATE key on the front panel of the analyzer to zero the device.
- 7.1.1.3 Set the safety analyzer GROUND switch to NORMAL. Set the POLARITY switch to OFF.
- 7.1.1.4 The safety analyzer shall indicate 0.1  $\Omega$  or less with its test lead applied to the following points:
  - --Cylinder yoke (if applicable)
  - --Serial port cable retaining nut on processor
  - --Vaporizers
  - --Push/pull handle
  - --GCX rails

(✓) 7.1.2 Circuit Isolation (If Applicable)

**NOTE:** This test is not applicable on machines with serial numbers 12191 to 12334.

7.1.2.1 With a multimeter set to its highest resistance range, check for continuity between the serial port cable retaining nut on processor and the O2 sensor connector pin shown in the illustration. There shall be no continuity between these points.



(✓) 7.1.3 Auxiliary Outlet Strip (if applicable)

**NOTE:** This test will check the auxiliary strip outlets for fault conditions such as open ground (>31  $\Omega$ ), reverse polarity, open line and open neutral. This is done each time the BIOTECH 501 PRO is powered up and allowed to cycle through its self test.

- 7.1.3.1 Shut off and unplug the safety analyzer. Remove the anesthesia machine plug from the analyzer, and plug it into the same outlet that was being used by the analyzer.
- 7.1.3.2 Plug the safety analyzer into the first outlet to be tested, and turn the analyzer power switch ON. Allow the analyzer to cycle through its Auto Test sequence. If no wiring fault is indicated, shut off the analyzer and move its plug to the next outlet. Test this outlet in the same manner, and continue until all convenience outlets on the auxiliary strip outlets are tested.

#### 7.1.4 Chassis Leakage Current

- 7.1.4.1 Turn the anesthesia machine System Power switch to ON and set the safety analyzer to the CHASSIS LEAKAGE CURRENT position.
- 7.1.4.2 Attach the safety analyzer test lead to a rear GCX rail.

(✓) 7.1.4.3 Record the total leakage current with the Polarity and Ground switches set as follows:

Ground	Polarity
Open	Normal
Normal	Normal
Open	Reversed
Normal	Reversed

Verify that the leakage current is 300 microamps or less in each of the switch positions (500 microamps or less for the 220/240 volt power supply option).

# (✓) 7.2 System Diagnostics

- 7.2.1 Connect the pipeline supply or open the cylinders.
- 7.2.2 Push the System Power switch to ON ( $\odot$ ).
- 7.2.3 Verify that the following is displayed and system diagnostics indicate a "Pass" condition:

SYSTEM DIAGNOSTICS		System Status
Watch Dog	Pass	Functional
System RAM	Pass	
Program Memory	Pass	
Video Test	Pass	
Interrupts	Pass	
A/D Converter	Pass	
NV RAM	Pass	
Serial Port	Pass	
Clock	Pass	
Speaker	Pass	
Main Power	Pass	
Battery	Pass	
Drä	iger	

Fabius GS SW XX

(✓) Record the machine software version on the header of the checklist form.

# (✓) 7.3 Battery Circuit

- 7.3.1 Press the Man Spont key, and press the rotary dial to confirm.
- 7.3.2 Unplug the AC power cord and verify the "Power Fail" message appears on the display within one minute.
- 7.3.3 Restore AC power to the machine and verify the "Power Fail" message disappears within one minute.

# (✓) 7.4 Configuration

- 7.4.1 Press the Standby key, then press the rotary key to confirm.
- 7.4.2 Press the Setup key, and press the rotary dial to confirm.

#### **Default Settings:**

- 7.4.3 Verify all parameters listed in the 'Default Settings' screen are adjustable.
- 7.4.4 Adjust the Alarm Volume to its highest setting and press the rotary dial to confirm.
- 7.4.5 Press the rotary dial once to return to the Setup screen.

# Configuration:

- 7.4.6 Using the rotary dial, scroll to Configuration and press the rotary dial to confirm.
- 7.4.7 Verify all parameters listed in the 'Configurations Settings' screen are adjustable and correct per local configurations. Press to confirm two times to exit Setup mode.

#### 7.5 Service Data

- 7.5.1 Press and hold the Home and Standby keys, and press the rotary dial. Verify the System Service screen appears.
- (✓) Verify on-screen serial number with machine serial number located on rear of unit, and record on header of PMS form.
- (🗸) 7.5.3 Record the Last Service Date, Hours Run Since Last Service, Total Hours Run, and Total Ventilator Hours Run on the PMS form.
  - 7.5.4 Press the rotary knob to go to the Main Service screen.
  - 7.5.5 Scroll to Preventative Maintenance, then to Activate.
  - 7.5.6 Change the Preventative Maintenance date to reflect next PM due date. Press the rotary dial once to return to the main service screen.

# **PMS PROCEDURE (continued)**

**FABIUS GS** 

<b>(✓</b> )	7.5.7	Inspect the condition of the ventilator (piston diaphragm) O-ring. Is
		the O-ring in good condition? (Y)

(\*)

7.5.8 If applicable, install the appropriate PM kit(s) and record in Parts Replacement section of PM form. See Parts Replacement Schedule on page 3.

#### 7.6 Calibrations

#### Fresh Gas Flow:

- 7.6.1 Scroll to Calibration and press to confirm.
- 7.6.2 Scroll to Fresh Gas Flow and confirm.
- 7.6.3 Follow on-screen instructions and perform Fresh Gas Flow calibration.
- (✓) 7.6.4 Verify Stored Zero indicates Pass (Y)
  - 7.6.5 Press the Exit key.

#### Pressure:

- 7.6.6 Scroll to Pressure and confirm.
- (\*) 7.6.7 Follow the on-screen instructions and perform the Zero calibration. Reconnect pressure line and ventilator hose to breathing system.
  - 7.6.8 Press the Exit key, then scroll to O2 and confirm.

#### O2 Offset:

(1) 7.6.9 Follow the on-screen instructions and perform the O2 zero calibration. Reassemble O2 housing and install the inspiratory dome plug in inspiratory dome.

#### PEEP:

- **NOTE:** Before performing the PEEP valve calibration, a valid pressure calibration must be performed. Otherwise, an 'Inv pres. cal' message will appear.
- 7.6.10 Press the Exit key; scroll to PEEP and confirm.
- (✓) 7.6.11 Follow the on-screen instructions to calibrate PEEP. Verify PEEP calibration indicates PASS (Y).
  - 7.6.12 Press Exit, then confirm (2x).

# 7.7 Site Configurations

7.7.1 Scroll to Configure and confirm.

#### O2 Position (virtual flowtubes):

(\*) Scroll to Flowmeter and confirm. Scroll to O2 Position and confirm. Select position of virtual flowmeter (left or right) in accordance with local requirements or customer demand. Press to confirm. record position on PMS form.

#### Gas Selection:

(✓)
 7.7.3 Press to confirm, scroll to Gas Selection and confirm. Verify Gas Selection type (2 or 3) is in accordance with machine configuration. Press to confirm (x2). Record selection type on PMS form.

#### Flowtube Resolution:

7.7.4 Scroll to Flowtube Res. and press to confirm. Scroll to change state and confirm. Scroll to change state in accordance with customer demand.

#### O2 Whistle:

(✓) 7.7.5 Press to confirm, scroll to O2 whistle. Verify O2 whistle selection (enabled or disabled) is in accordance with local requirements or customer demand. Press to confirm (x2). Record position on PMS form.

#### Alarms:

- (✓) Scroll to No Fresh Gas and confirm. Verify state of No Fresh Gas alarm is enabled. Press to confirm (x2). Record position on PMS form.
- 7.7.7 Scroll to Fresh Gas Low Alarm. Verify Fresh Gas Low Alarm position (enabled or disabled) is set to enabled position. Press to confirm (x2). Record position on PMS form.
- (✓) 7.7.8 Scroll to Threshold Low and confirm. Verify state of Threshold Low Alarm is enabled. Press to confirm (x2). Record position on PMS form.

#### Pressure:

- (✓) Scroll to Ambient Pressure and confirm. Turn rotary dial to adjust. Press to confirm (x2). Record pressure setting on PMS form.
  - **NOTE:** Using the table found on the following page, set the ambient pressure (mbar) in accordance with the local elevation. To verify the local elevation, contact the nearest regional airport, or contact:

DMI - Technical Support - 1-800-543-5047 DMT - Tech Line - 49-451-882-4222

- 7.7.10 Scroll to Plateau/Mean Dis and verify setting is in accordance with customer demand. Press to confirm (x3).
- 7.7.11 If Software Version 2.X is installed, scroll to the 'System Settings/ Model Type' screen and confirm. Verify 'Model Type' listed is consistent with actual unit.

**NOTE:** Machines from the factory are configured with the appropriate model type. Other than performing a software download or PCB replacement, the model type should not be changed. Changing the model type will disable some ventilator options and will require reconfiguration.

#### Serial Ports:

(\*) 7.7.12 Scroll to Serial Ports and confirm. Verify parameters are adjustable to the following protocols. If necessary, set the protocols for any third party monitoring device connected to the machine. Refer to the Fabius GS Operator's Manual and third party Operator's Manual.

Baud Rate:	1200, 2400, 4800, 9600, 19200, 38400
Parity:	NONE, ODD, EVEN
Stop Bits:	1, 2
Data Bits:	7, 8
Protocol:	Vitalink - Medibus

**NOTE:** It is important to ensure that communication protocols selected on each host and external device are correct. Vitalink and Medibus protocols are similar and if not set identically on each device, inaccurate data may be displayed on the remote device.

7.7.13 Press Standby key to exit.

Elevation Range in Feet	Elevation Range in Meters	Barometric Pressure Setting
-200 - 199	-60 - 60	1013
200 - 599	61 - 182	1000
600 - 999	183 - 304	985
1000 - 1399	305 - 426	970
1400 - 1799	427 - 548	960
1800 - 2199	549 - 670	945
2200 - 2599	671 - 792	930
2600 - 2999	793 - 914	920
3000 - 3399	915 - 1036	905
3400 - 4199	1037 - 1158	890
3800 - 4199	1159 - 1280	880
4200 - 4599	1281 - 1401	865
4600 - 4999	1402 - 1523	855
5000 - 5399	1524 - 1645	840
5400 - 5799	1646 - 1767	830
5800 - 6199	1768 - 1889	820
6200 - 6599	1890 - 2011	805
6600 - 6999	2012 - 2133	795
7000 - 7399	2134 - 2255	785
7400 - 7799	2256 - 2377	770
7800 - 8199	2378 - 2499	760
8200 - 8999	2500 - 2620	750
8600 - 8999	2621 - 2742	740
9000 - 9399	2743 - 2864	730

# (√) 7.8 Scavenger

# 7.8.1 AGS Scavenger

Scavenger Cleaning

- 7.8.1.1 Remove all scavenger hoses one at a time and drain all accumulated moisture. Inspect all scavenger hoses for deterioration and replace any worn hoses.
- 7.8.1.2 Disconnect the hospital vacuum source from the scavenger.
- 7.8.1.3 Remove the reservoir canister from the scavenger by partial turn counter-clockwise of the canister.
- 7.8.1.4 Remove and inspect the silencer; replace if needed.
- 7.8.1.5 Remove the flowmeter from the scavenger by turning the mounting nut counter-clockwise. Inspect the tube and clean with compressed air if needed.
- 7.8.1.6 Reassemble the scavenger assembly, and reactivate the vacuum source.

Scavenger, AGS Functional Test

- 7.8.1.7 Verify vacuum hose is connected to one of the two gas supply connections.
- 7.8.1.8 Verify the additional gas surplus connection is plugged.
- 7.8.1.9 Verify all hose connections to the scavenger are complete at all destinations.
- 7.8.1.10 Verify vacuum waste disposal system at manifold is active.
- 7.8.1.11 Reinstall canister and adjust scavenger flow control valve; verify float moves freely between the upper and lower limits.

# 7.8.2 Passive Scavenger

Passive Scavenger Cleaning

- 7.8.2.1 Inspect all scavenger hoses for signs of wear and deterioration. Replace any worn hoses.
- 7.8.2.2 Remove the anti-occlusion cage from the passive scavenger by unscrewing it.

- 7.8.2.3 Inspect the filter.
- 7.8.2.4 If necessary, remove the filter for cleaning. Brush any accumulated lint of dust off the filter. The filter can be further cleaned with a low flow of clean air or oxygen.
- 7.8.2.5 Place the filter back, making sure that it lays flat on the valve port orifice.
- 7.8.2.6 Reinstall the anti-occlusion cage on the scavenger body, making sure the filter is properly seated.

### Passive Scavenger Functional Test

- 7.8.2.7 Check for moisture accumulation in the breathing and scavenger hoses. Remove and moisture found.
- 7.8.2.8 Short-circuit the COSY breathing system inspiratory and expiratory valves with a 2 mm breathing hose.
- 7.8.2.9 Install a breathing bag on the COSY breathing system.
- 7.8.2.10 Set the COSY breathing system APL valve to SPONT.
- 7.8.2.11 Open the oxygen flow control valve to a flow of 10 L/min and occlude the passive scavenger exhaust port connection.
- 7.8.2.12 After the breathing bag inflates, the absorber systems' breathing pressure gauge must indicate a pressure of less than 5 cm H2O.
- 7.8.2.13 Systems that are not equipped with a pressure gauge, observe the generated pressure waveform, set the threshold to 5 cm H2O. The pressure waveform shall not rise and remain above the dotted threshold trace during this performance test.

# 7.9 Breathing System

**(✓**) 7.9.1 Breathing System Inspection **(✓**) Record the serial number (located on the side of the COSY) on 7.9.1.1the PMS form. 7.9.1.2 Remove the inspiratory and the expiratory valve domes. 7.9.1.3 Is there a broken or bent pin on the valve assembly? Inspiratory (N) Expiratory (N) 7.9.1.4 Is there a broken pin on the valve domes? Inspiratory (N) Expiratory (N) Is the valve disc in good condition? 7.9.1.5 Inspiratory (Y) Expiratory (Y) 7.9.1.6 Is there excessive wear on the valve craters? Inspiratory (N) Expiratory (N) 7.9.1.7 Are the valve dome washers in good condition? \_\_\_ (Y) 7.9.1.8 Reinstall the inspiratory and expiratory valve domes. Un-screw the 22 mm expiratory port. Is the O-ring inside the 7.9.1.9 port and 22mm taper in good condition? (Y) 7.9.1.10 Remove the flow sensor from the breathing system housing. Is the O-ring inside housing in good condition? (Y) 7.9.1.11 Reinstall the flow sensor and expiratory port. 7.9.1.12 Remove the canister and inspect the canister, gaskets, and condition of soda lime. Are these components in good condition?  $\underline{\hspace{1cm}}(Y)$ 7.9.1.13 Remove the breathing pressure gauge from its mount and inspect the O-rings in the mount and on the 90° hose connection if applicable. 7.9.1.14 Is the breathing pressure gauge in good condition and set at zero (0)? \_\_\_ (Y) (if applicable) 7.9.1.15 Inspect the O-rings on the inspiratory dome plug assembly and O2 sensor housing. Are the O-rings in good condition? \_\_\_(Y)

	7.9.1.16	Examine all pneumatic hoses connecting from the interface panel to the breathing system. Are the hoses kink free and in good condition? $\underline{\hspace{1cm}}(Y)$
	7.9.1.17	Inspect the breathing circuit and manual breathing bag. Is the breathing circuit and manual breathing bag in good condition? $\underline{\hspace{1cm}}(Y)$
	7.9.1.18	Inspect the ventilator hose and associated O-rings connected between breathing system and machine. Are the hose and O-rings in good condition?(Y)
	7.9.1.19	Inspect the fresh gas hose connected to the breathing system. Is the fresh gas connector and washer in good condition? $\underline{\hspace{1cm}}(Y)$
	7.9.1.20	Inspect APL valve labeling for legibility. Are all markings on APL valve easy to see and legible?(Y)
	7.9.1.21	Inspect the scavenger gas connection on the breathing system. Is the scavenger connector in good condition? $\underline{\hspace{1cm}}(Y)$
	7.9.2 Fresh	Gas Leak
	7.9.2.1	Push the System Power switch OFF ( $\overset{ullet}{\bigcirc}$ ).
	7.9.2.2	Remove the fresh gas connector from the breathing system.
	7.9.2.3	Connect the fresh gas hose from the breathing system to the fresh gas leak test fixture (4113119 modified) or equivalent, via the fresh gas test connector 4117361.
	7.9.2.4	Connect a digital pressure manometer to the fresh gas leak test device.
	7.9.2.5	Apply 50 cm $\rm H_2O$ of pressure to the system.
<b>( ✓</b> )	7.9.2.6	After thirty (30) seconds, what is the pressure on the manometer? (>40 cm $\rm{H}_2O)$
	7.9.2.7	If applicable, turn on the left mounted vaporizer to the first graduated marking.
	7.9.2.8	Apply 50 cm $\rm H_2O$ of pressure to the system.
<b>(√</b> )	7.9.2.9	After thirty (30) seconds, what is the pressure on the manometer? (>40 cm $\rm H_2O)$
	7.9.2.10	Turn off the vaporizer.

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# PMS PROCEDURE (continued)

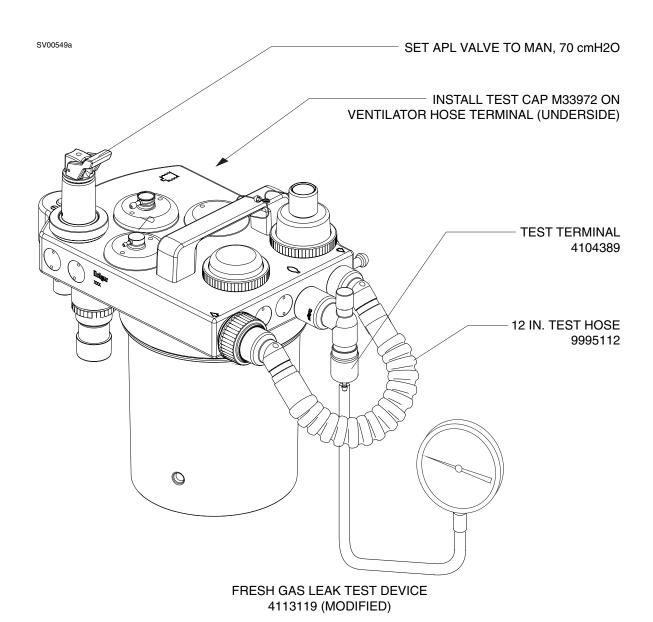
**FABIUS GS** 

- (\*) 7.9.2.11 If applicable, turn on the right mounted vaporizer to the first graduated marking; repeat Steps 7.9.2.5 thru 7.9.2.10 \_\_\_ (>40 cm  $\rm H_2O$ )
  - 7.9.2.12 Remove the test equipment from the fresh gas hose.
  - 7.9.2.13 Push the System Power switch ON (⊙).
  - 7.9.2.14 Open the  $\rm O_2$  flow control valve to 5 L/min., purge the system for 5 seconds, then close the  $\rm O_2$  flow control valve.
  - 7.9.2.15 Push the System Power switch OFF (O).
  - 7.9.2.16 Reconnect the fresh gas connector from the machine to the freshgas outlet connector on the breathing system.

# (✓) 7.9.3 Breathing System Leak

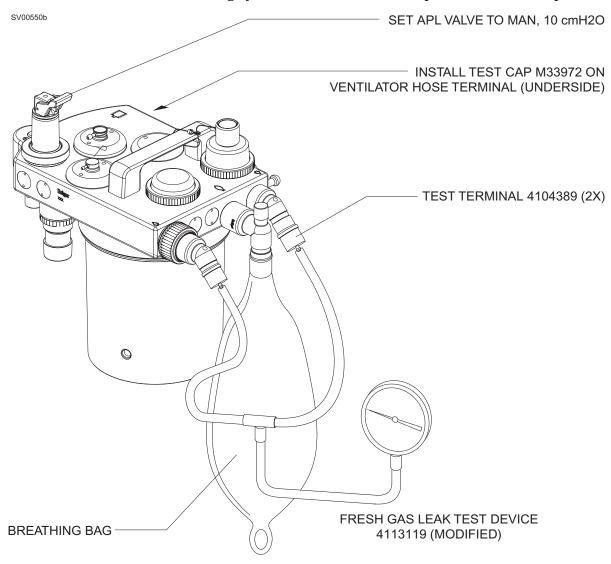
**NOTE:** Use the appropriate column in the following table - according to the software version of the machine you are testing:

	$Software \leq 1.20$	$Software \geq 1.30 \ (USA)$ $Software \geq 1.2x \ (non\text{-}USA)$	
7.9.3.1	Verify the System Power switch is On		
7.9.3.2	Press Run Leak Test softkey	Press the Leak/Compl Test softkey	
7.9.3.3	Close all flow control valves		
7.9.3.4	Using a test terminal attach a digital manometer to the 22mm bag mount connector as shown in the following illustration	Perform the on-screen instructions	
7.9.3.5	Interconnect the inspiratory valve and expiratory valves with a 12-inch test hose (9995112)		
7.9.3.6	Set the APL valve to 70 cmH2O and to MAN position		
7.9.3.7	Remove the ventilator hose from the breathing system and install a test cap (M33972)		
7.9.3.8	Adjust O2 flow to maintain 40 $\rm cmH_2O$ pressure on the digital manometer		
7.9.3.9	What is the O2 flow mL/min. as indicated on the display? (<100 mL/min. flow leakage)	Verify all applicable tests indicate a Pass condition	
7.9.3.10	What is the pressure difference on the Paw cm H2O display compared to digital manometer? (38 - 42 cmH2O)		
7.9.3.11	If applicable, does the optional breathing pressure gauge agree with the readings in the previous step? (Y)		
7.9.3.12	Remove test equipment		



# 7.9.4 APL Valve Verification

- 7.9.4.1 Connect a digital manometer between the inspiratory and expiratory ports of the breathing system (using two test terminals and modified 4113119 fresh gas leak test device). See following illustration.
- 7.9.4.2 Attach a breathing bag to the bag terminal connector on the breathing system and install a test cap on the ventilator port.



	Lever Style APL Valve			Rotary Knob Style APL Valve		
	7.9.4.3	Verify the fresh gas hose is connected to the breathing system.				
	7.9.4.4	Verify the APL valve is in the MAN position and set to 10 cmH2O.				
	7.9.4.5	Activate the flush to inflate the reservoir bag, then release.				
<b>( /</b> )	7.9.4.6	Adjust the O2 and Air flows to 10 L/min. (20 L/min. total). Verify pressure remains between 8 and 12 cmH2O.				
<b>( /</b> )	7.9.4.7	Repeat Steps 7.9.4.4 thru 7.9.4.8 with the following settings, and verify APL valve accuracy:  Spec (cm H2O)		Repeat Steps 7.9.4.4 thru 7.9.4.8 with the following settings and verify APL Valve accuracy:		
	APL Valve			APL Valve	Spec (c	m H2O)
	Setting	Low	High	Setting	Low	High
	30	27	33	40	34	46
	50	45	55			

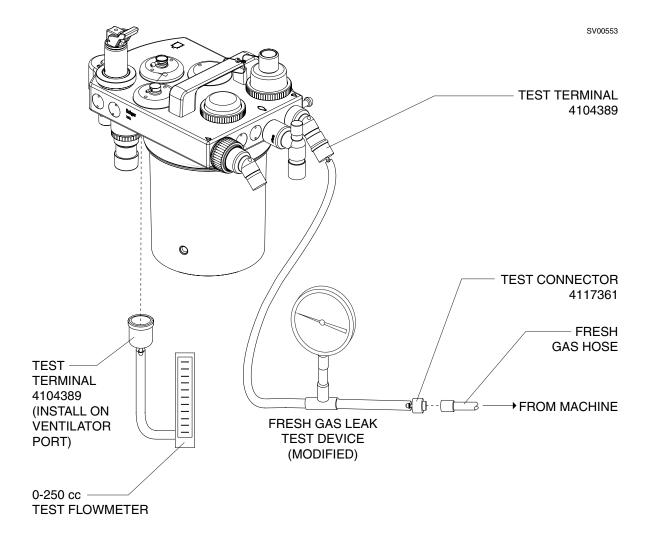
7.9.4.8 Close the O2 and Air flow control valves.

7.9.4.9 Remove the digital manometer and associated test equipment from the inspiratory & expiratory valve ports and bag terminal.

# 7.9.5 Inhalation and Exhalation Valves

# Inhalation:

- 7.9.5.1 Install test terminal on the 22 mm inspiratory connector.
- 7.9.5.2 Connect 0 250 cc flowmeter (S000081) with a test terminal as shown, to the ventilator port of the breathing system.



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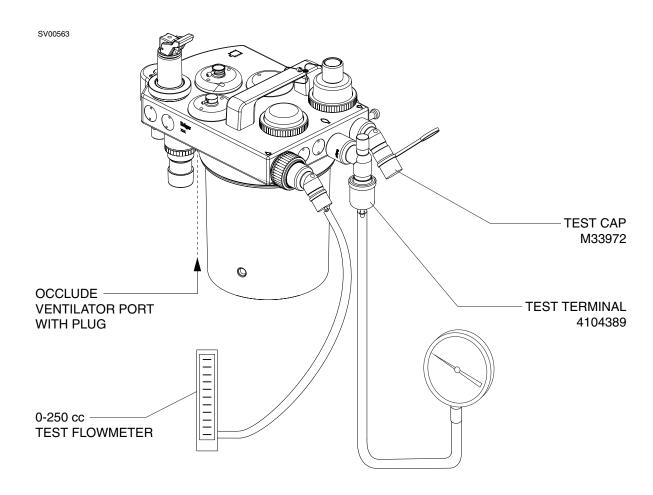
	7.9.5.3	Remove the freshgas hose from the breathing system and connect it to the freshgas leak connector (4117163).
	7.9.5.4	Connect the fresh gas leak connector to the fresh gas leak test device (4113119 modified) as shown.
	7.9.5.5	Increase O2 flow to maintain 30 cmH2O on the digital manometer.
<b>(</b> ✓)	7.9.5.6	What is leakage as shown on 0 - 250 cc flowmeter? ( $<60$ cc/min.)
	7.9.5.7	Remove all test equipment from breathing system and disconnect digital manometer from fresh gas hose.

#### Exhalation:

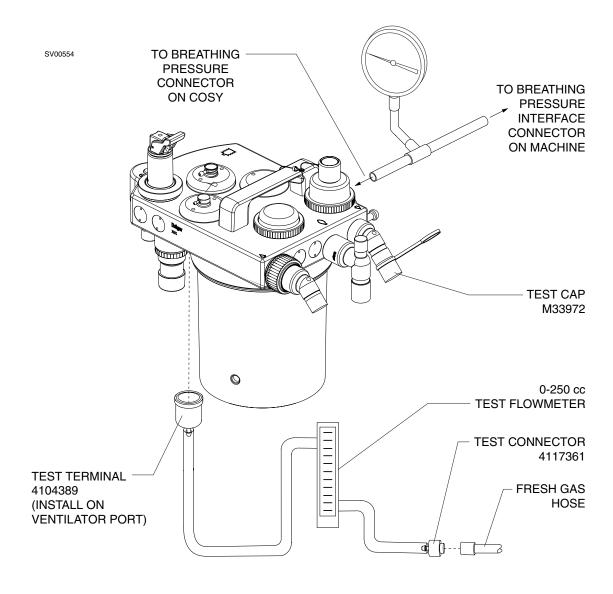
- 7.9.5.8 Occlude ventilator and inspiratory port, each with test cap M33972.
- 7.9.5.9 Connect a digital manometer to bag mount and 0-250 cc test flowmeter to thre expiratory port as shown.
- 7.9.5.10 Connect Fresh gas hose from machine to fresh gas port of breathing system.
- 7.9.5.11 Slowly increase O2 flow to build up and maintain 30 cmH2O/mbar on digital manometer.

**NOTE:** Verify pressure on digital manometer. Pressure decay is not visible on system cmH2O pressure gauge.

- (✓) 7.9.5.12 Verify leakage is <60 cc/min. as indicated on test flowmeter.
  - 7.9.5.13 Remove all test equipment except for test cap on inspiratory port.



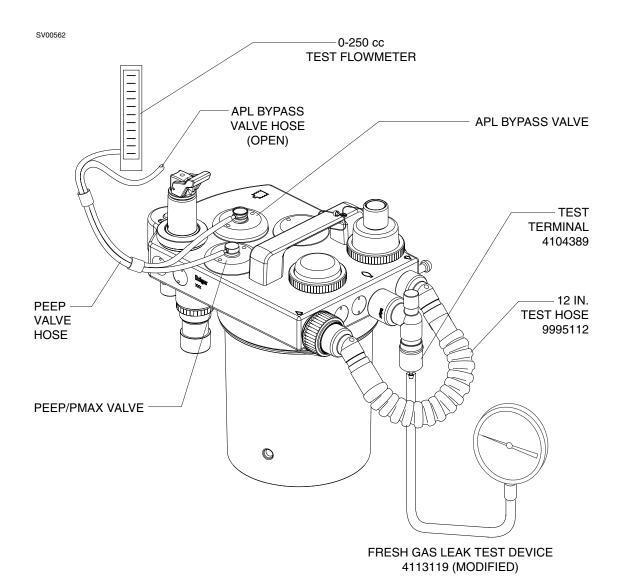
- 7.9.6 Reverse Flow Test (Fresh Gas Decoupling Valve)
  - 7.9.6.1 Verify the breathing bag port, fresh gas connection and expiration port connections are open and not occluded.
  - 7.9.6.2 Connect a digital pressure meter between the COSY pressure port and the pressure hose from the machine as shown.
  - 7.9.6.3 Verify occlusion of the inspiration port with test cap M33972.
  - 7.9.6.4 Connect the fresh gas hose to the ventilator port on the COSY with the test connector as shown.



FABIUS GS		PMS PROCEDURE (continued)
	7.9.6.5	Verify the APL valve is in the MAN position and set to 70 cmH2O.
	7.9.6.6	Slowly increase O2 flow to maintain 40 cmH2O on the digital pressure meter.
(✔)	7.9.6.7	Verify the flow on the 0-250 cc test flowmeter indicates less than 10 mL/min. (0.01 L/min.).
	7.9.6.8	Close the O2 flow control valve.
	7.9.6.9	Remove the occlusion plugs and test equipment from the breathing system.
	7.9.6.10	Reconnect fresh gas hose to breathing system; connect ventilator hose to vent port and breathing system.

#### 7.9.7 Leakage Control Port

- 7.9.7.1 Disconnect the APL and PEEP control hoses from the interface panel at rear of machine.
- 7.9.7.2 Connect the PEEP control hose to the input of the 0-250 cc test flowmeter.



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PMS PROCEDURE (continued)

	7.9.7.3	Short circuit the inspiratory and expiratory ports, attach a test terminal to the breathing bag port and attach a digital manometer to the test terminal.
	7.9.7.4	Increase O2 flow to maintain 40 cmH2O on the digital manometer.
$(\checkmark)$	7.9.7.5	Verify the test flowmeter indicates < 10 cc/min.
	7.9.7.6	Remove the 0-250 cc test flow meter, digital manometer and short circuit hose from machine. $$
	7.9.7.7	Return all hose connections to their normal positions.

# **PMS PROCEDURE (continued)**

**FABIUS GS** 

# $(\checkmark)$ 7.10 Vapor Interlock System

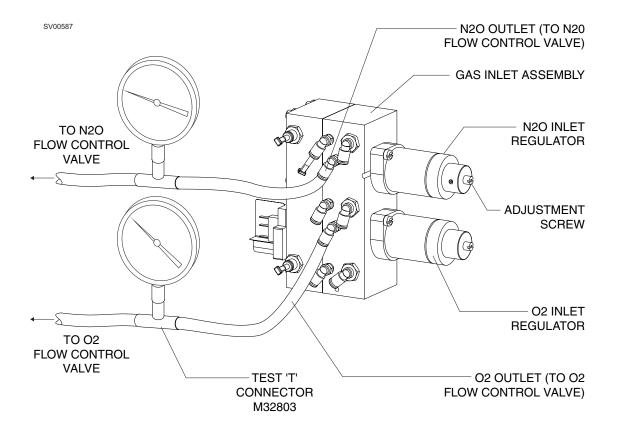
7.10.1	Set all vapors to zero (0).
7.10.2	Adjust the handwheel on the left vapor to any concentration above zero $(0)$ .
7.10.3	Is it possible to adjust the right vapor? $\_\_(N)$
7.10.4	Adjust the handwheel on the left vapor to zero $(0)$ .
7.10.5	Adjust the handwheel on the right vapor to any concentration above zero $(0)$ .
7.10.6	Is it possible to adjust the left vapor? $\_\_$ (N).
7.10.7	Adjust the handwheel on the right vapor to zero (0).
7.10.8	If applicable, adjust handwheel of center vaporizer to any concentration above zero (0).
7.10.9	Is it possible to adjust the left or right vaporizer?(N)

# 7.11 Yokes & Gauges

<b>(√</b> )	7.11.1 Yo	kes & Check Valves (if applicable)
	7.11.1	.1 Turn the System Power switch Off.
	7.11.1	.2 Disconnect all pipeline hoses and close all cylinder valves.
	7.11.1	.3 Remove cylinder or yoke plug from each yoke assembly.
	7.11.1	.4 Do all the yoke handles adjust smoothly?(Y)
	7.11.1	.5 Are the two (2) yoke pins installed securely in each yoke? (Y)
	7.11.1	.6 Is there only one (1) cylinder washer on each yoke assembly? $\underline{\hspace{1cm}}$ (Y)
	7.11.1	.7 Is there a yoke plug attached to each yoke assembly? $\underline{\hspace{1cm}}$ (Y)
	7.11.1	.8 Is the proper gas I.D. label affixed to each yoke assembly?(Y
	7.11.1	.9 Attach a cylinder to each yoke assembly, open the cylinder valve, let the pressure stabilize, close the cylinder valve, and remove the cylinder from the yoke assembly.
	7.11.1	.10 Does the yoke check valve assembly prevent the escape of excessive pressure? (Y)
	7.11.1	.11 Attach the cylinders to the yokes.
<b>( ✓</b> )	7.11.2 Cy	/linder Gauges (if applicable)
	7.11.2	.1 Are the pressure gauges correct for the gases indicated by the flowmeters? (Y)
	7.11.2	.2 Bleed all pressure from the cylinder circuits using the flow control valves.
	7.11.2	.3 Are the cylinder gauges at zero (0) PSI? (Y)
	7.11.2	.4 Open the cylinder valves.
	7.11.2	.5 Do the cylinder pressure gauges respond properly? (Y)

#### 7.12 Gas Inlet Regulator Output

- 7.12.1 O2 Inlet Regulator
  - 7.12.1.1 Bleed all cylinder and pipeline pressures. Disconnect all cylinders and pipeline hoses and remove rear panel to access gas inlet assembly.
  - 7.12.1.2 Remove the pneumatic hose from the O2 outlet of the gas inlet block and interconnect a digital manometer as shown.



- 7.12.1.3 Reconnect the O2 pipeline hose to the O2 pipeline inlet connector and pressurize the O2 supply.
- 7.12.1.4 Set the O2 flow to 4 L/min.

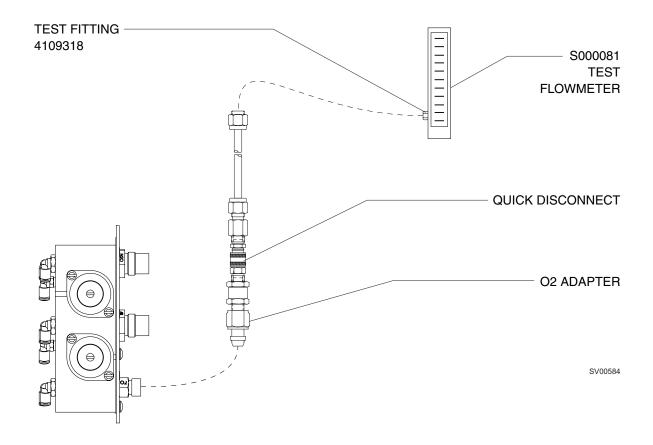
**(✓)** 7.12.1.5 After the digital manometer stabilizes, what is the regulator output pressure? psi (28 - 32 psi) 7.12.1.6 Deplete O2 pressure from the pipeline supply. 7.12.1.7 Close the flow control valve and disconnect the O2 pipeline hose from the inlet. 7.12.1.8 Remove test equipment and reconnect the O2 pneumatic hose leading from the O2 flow control valve to the O2 connector on the inlet block. N2O Inlet Regulator 7.12.2 7.12.2.1 Disconnect the N2O pneumatic hose from the outlet connector on the gas inlet block that connects to the N2O flow control valve. 7.12.2.2 Interconnect a digital manometer between the N2O outlet connector and the hose removed in the previous step. See illustration on previous page. 7.12.2.3 Reconnect the O2 and N2O pipeline hoses to the inlet block and activate the pipeline supplies. 7.12.2.4 Set the O2 and N2O flows to 4 L/min. After the digital **(✓)** manometer stabilizes, what is the N2O regulator output pressure? \_\_\_psi (28 - 32 psi) 7.12.2.5 Deplete the O2 and N2O pipeline pressures. 7.12.2.6 Close the O2 and N2O flow control valves and disconnect both pipeline hoses from the inlet block.

7.12.2.7 Remove test equiupment and reconnect the N2O hose from the flow control valve to the N2O outlet on the inlet block.

#### 7.12.3 Pipeline Check Valves

#### O2 Pipeline Check Valve:

- 7.12.3.1 Attach a Swagelock fitting (P/N 4109318) to the inlet of the S000081 test flowmeter.
- 7.12.3.2 Detach the hose from the Pressure Test adapter (P/N 4114807) gauge assembly and attach it to the inlet of the test flowmeter as shown.
- 7.12.3.3 Attach the appropriate O2 adapter to the O2 connector on the inlet block, and connect the other end of the hose with the quick disconnect fitting to the adapter as shown.



(1) 7.12.3.4 Open an O2 (reserve) cylinder valve. What is the flow as indicated on the test flowmeter? \_\_\_cc  $\leq$ 5 cc/min.

**PMS PROCEDURE (continued)** 

N2O Pipeline Check Valve (if applicable)

- 7.12.3.5 Attach the appropriate N2O adapter to the N2O connector on the inlet block, and transfer the end of the hose with the quick disconnect fitting to the N2O adapter.
- ( $\checkmark$ ) 7.12.3.6 Open the N2O (reserve) cylinder. What is the flow as indicated on the test flowmeter? \_\_\_cc  $\leq$ 5 cc/min.

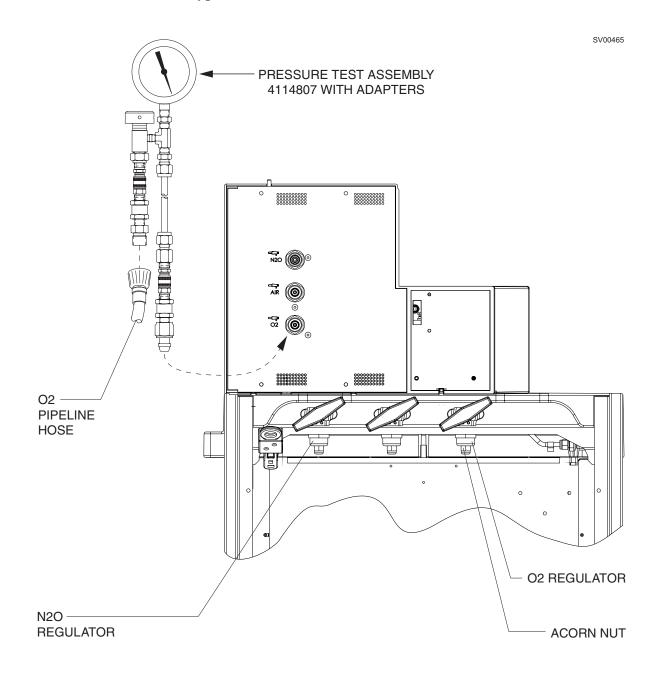
Air Pipeline Check Valve (if applicable)

- 7.12.3.7 Attach the appropriate Air adapter to the Air connector on the inlet block, and transfer the end of the hose with the quick disconnect fitting to the Air adapter.
- (✓) 7.12.3.8 Open the Air (reserve) cylinder. What is the flow as indicated on the test flowmeter? \_\_\_cc ≤5 cc/min.
  - 7.12.3.9 Remove all test equipment and reinstall the gas inlet block and back panel on the machine.

#### 7.13 Cylinder Regulator & Pipeline Gauges

Minimum cylinder pressure requirements for this test are: N2O: 600 psi; O2, Air: 1000 psi.

- (✓) 7.13.1 N2O Cylinder Regulator (if applicable)
  - 7.13.1.1 Configure test gauge 4114807 using the appropriate adapters between the pipeline inlet of machine and central supply hose. A typical test connection is shown below (O2 illustrated).



7.13.1.2	Connect the test fixture hose to the machine's nitrous oxide pipeline inlet.
7.13.1.3	Does the back panel correctly identify the nitrous oxide inlet? $\underline{\hspace{1cm}}(Y)$
7.13.1.4	Connect the nitrous oxide pipeline supply hose to the test fixture.
7.13.1.5	Open the nitrous oxide and the oxygen cylinder valves.
7.13.1.6	Set the oxygen and nitrous oxide flows to 4 L/min.
7.13.1.7	Depress the push button on the test device.
( <b>✓</b> ) 7.13.1.8	Release the push button. After the pressure decay stabilizes, what is the regulator output pressure?psi (32 - 40)
NOTE:	f a pressure decrease does not occur, either the hospital's supply pressure is too low or the regulator pressure is set too high.
( <b>✓</b> ) 7.13.2 N20	) Pipeline Gauge Accuracy
7.13.2.1	Close the nitrous oxide cylinder valve and drain all nitrous oxide pressure.
7.13.2.2	Depress and hold the push button on the test device.
7.13.2.3	Does the nitrous oxide gauge respond properly? $\underline{\hspace{1cm}}(Y)$
(✓) 7.13.2.4	After the pressure stabilizes, are the indicated pressures on the test gauge and the nitrous oxide pipeline pressure gauge within the normal operating range? 41 - 87 psi (non-USA), 50 - 55 psi (USA).

- 7.13.3 N2O Pipeline Leak
  - 7.13.3.1 Close the nitrous oxide flow control valve.
  - 7.13.3.2 Release the test device push button.
- ( $\checkmark$ ) 7.13.3.3 After 30 seconds, what is the pressure loss? \_\_\_psi (<5)
  - 7.13.3.4 Remove the test equipment and reconnect the nitrous oxide pipeline hose.
- (✓) 7.13.4 Air Cylinder Regulator
  - 7.13.4.1 Configure the test gauge using the appropriate adapters between the pipeline inlet of machine and central supply hose.
  - 7.13.4.2 Connect the test fixture hose to the machine's air pipeline inlet.
  - 7.13.4.3 Does the back panel correctly identify the air inlet? \_\_\_(Y)
  - 7.13.4.4 Connect the air pipeline supply hose to the test fixture.
  - 7.13.4.5 Set the air flow to 4 L/min.
  - 7.13.4.6 Depress the push button on the test device.
- (\*) 7.13.4.7 Release the push button. After the pressure decay stabilizes, what is the regulator output pressure? \_\_\_psi (based upon cylinder pressure as given in the following table)

Cylinder Pressure (psi)	Compensated Regulator output tolerances (-4/+2)
2000	27 - 33 (*30 - 36)
1800	28 - 34 (*31 - 37)
1600	29 - 35 (*32 - 38)
1400	30 - 36 (*33 - 39)
1200	31 - 37 (*34 - 40)
1000	32 - 38 (*35 - 41)

<sup>\*</sup> Canada settings

**NOTE:** If a pressure decrease does not occur, either the hospital's supply pressure is too low or the regulator pressure is set too high.

(✔)	7.13.5 Air P	ipeline Gauge Accuracy
	7.13.5.1	Close the air cylinder valve and drain all air pressure.
	7.13.5.2	Depress the push button on the test device.
	7.13.5.3	Does the air gauge respond properly? $\underline{\hspace{1cm}}(Y)$
	7.13.5.4	After the pressure stabilizes, are the indicated pressures on the test gauge and the air pressure gauge within the normal operating range? 41 - 87 psi (non-USA), 50 - 55 psi (USA).
	7.13.6 Air P	ipeline Leak
	7.13.6.1	Close the air flow control valve
	7.13.6.2	Release the test device push button
(✔)	7.13.6.3	After thirty (30) seconds, what is the pressure loss?psi ( $<$ 5)
	7.13.6.4	Remove the test equipment and reconnect the air pipeline hose.
(✔)	7.13.7 O2 C	Cylinder Regulator
	7.13.7.1	Configure a test gauge 4114807 using the appropriate adapters between the pipeline inlet of machine and central supply hose.
	7.13.7.2	Connect the test fixture hose to the machine's oxygen pipeline inlet.
	7.13.7.3	Connect the oxygen pipeline supply hose to the test fixture.
	7.13.7.4	Does the back panel correctly identify the oxygen inlet? $\underline{\hspace{1cm}}(Y)$
	7.13.7.5	Set the oxygen flow to 4 L/min.
	7.13.7.6	Depress the push button on the test device.

(\*) 7.13.7.7 Release the push button. After the pressure decay stabilizes, what is the regulator output pressure? \_\_\_psi (based upon cylinder pressure as given in the following table)

Cylinder Pressure (psi)	Compensated Regulator output tolerances (-4/+2)
2000	27 - 33 (*30 - 36)
1800	28 - 34 (*31 - 37)
1600	29 - 35 (*32 - 38)
1400	30 - 36 (*33 - 39)
1200	31 - 37 (*34 - 40)
1000	32 - 38 (*35 - 41)

<sup>\*</sup> Canada settings

**NOTE:** If a pressure decrease does not occur, either the hospital's supply pressure is too low or the regulator pressure is set too high.

- (✓) 7.13.8 O2 Pipeline Gauge Accuracy
  - 7.13.8.1 Close the oxygen cylinder valve and drain all oxygen pressure.
  - 7.13.8.2 Depress the push button on the test device.
  - 7.13.8.3 Does the oxygen gauge respond properly? (Y)
  - 7.13.8.4 After the pressure stabilizes, are the indicated pressures in the test gauge and the oxygen pressure gauge within the normal operating range? 41 87 psi (non-USA), 50 55 psi (USA).
  - 7.13.9 O2 Pipeline Leak
    - 7.13.9.1 Release the test device push button
- ( $\checkmark$ ) 7.13.9.2 After thirty (30) seconds, what is the pressure loss? \_\_\_psi (<5)

#### 7.14 High Pressure Leak

- 7.14.1 Oxygen High Pressure Leak
  - 7.14.1.1 Verify the System Power switch is OFF.
  - 7.14.1.2 Open the oxygen cylinder valve.
  - 7.14.1.3 Let the pressure stabilize.
  - 7.14.1.4 Close the oxygen cylinder valve and remove the cylinder.
  - 7.14.1.5 Observe the oxygen cylinder pressure gauge.
- ( $\checkmark$ ) 7.14.1.6 After two (2) minutes, what is the pressure loss? \_\_\_ PSI (<50)
  - 7.14.1.7 Attach the cylinder.
  - 7.14.2 Nitrous Oxide High Pressure Leak (if applicable)
    - 7.14.2.1 Turn the System Power switch to ON.
    - 7.14.2.2 Open one (1) oxygen cylinder valve and one (1) nitrous oxide cylinder valve.
    - 7.14.2.3 Adjust the oxygen flow to 4 L/min.
    - 7.14.2.4 Let the pressure stabilize.
    - 7.14.2.5 Close the nitrous oxide cylinder valve and remove the cylinder.
    - 7.14.2.6 Observe the nitrous oxide cylinder pressure gauge.
- ( $\checkmark$ ) 7.14.2.7 After two (2) minutes, what is the pressure loss? \_\_\_ PSI (<50)
  - 7.14.2.8 Attach the cylinder.
  - 7.14.2.9 Close the oxygen flow control valve.

7.14.5 All High Flessure Legi	7.14.3	Air High I	Pressure	Leal
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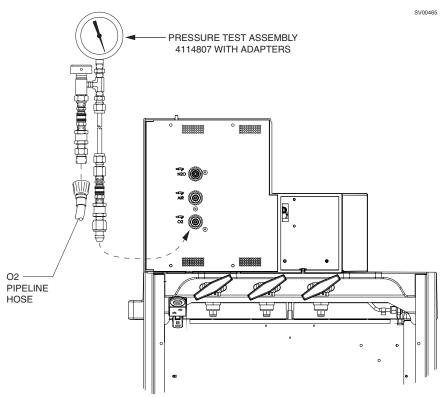
- 7.14.3.1 Turn the System Power switch to ON.
- 7.14.3.2 Open one (1) oxygen cylinder valve and the air cylinder valve.
- 7.14.3.3 Adjust the oxygen flow to 4 L/min.
- 7.14.3.4 Let the pressure stabilize.
- 7.14.3.5 Close the air cylinder valve and remove the cylinder.
- 7.14.3.6 Observe the air cylinder pressure gauge.
- ( $\checkmark$ ) 7.14.3.7 After two (2) minutes, what is the pressure loss? \_\_\_ PSI (<50)
  - 7.14.3.8 Attach the cylinder.
  - 7.14.3.9 Close the oxygen flow control valve.

#### 7.15 Oxygen Supply Failure Protection

- (✓) 7.15.1 Nitrous Oxide (if applicable)
  - 7.15.1.1 Open and close the oxygen cylinder valve.
  - 7.15.1.2 Open the nitrous oxide cylinder valve.
  - 7.15.1.3 Set the  $O_2$  and  $N_2O$  flows to 4 L/min.
  - 7.15.1.4 Does the flow of nitrous oxide cease when the oxygen flow is depleted?  $\underline{\hspace{1cm}}$  (Y)
  - 7.15.1.5 Connect the  $O_2$  pipeline supply.
  - 7.15.1.6 Close the nitrous oxide cylinder valve and bleed the pressure from the circuit.
  - 7.15.1.7 Connect the  $N_2O$  pipeline supply.
  - 7.15.1.8 Disconnect the  $O_2$  pipeline supply.
  - 7.15.1.9 Does the flow of nitrous oxide cease when the oxygen pressure is depleted?  $\underline{\hspace{1cm}}$  (Y)
  - 7.15.1.10 Close the nitrous oxide flow control valve.
  - 7.15.1.11 Disconnect the  $N_2O$  pipeline supply.

- 7.15.2 Oxygen Supply Pressure Alarm
  - 7.15.2.1 If not already connected, connect the Pressure Test Assembly (P/N 4114807) with  $\rm O_2$  adapters between the central supply hose and the machine.
  - 7.15.2.2 Open and close an oxygen cylinder.
  - 7.15.2.3 Set the oxygen flow to 0.5 L/min.
  - 7.15.2.4 Depress and release the test device push button.
- (✓)

  7.15.2.5 What is the pressure on the test gauge when the "O2 SUPPLY LOW !!!" message and associated red indicator appear? \_\_\_ PSI (16 24)
- (✓) 7.15.2.6 Does the "O2 SUPPLY LOW!!!" message appear on the display? \_\_\_(Y)
  - 7.15.2.7 Bleed the remaining  ${\rm O}_2$  pressure from the system, then close the flow control valve.
  - 7.15.2.8 Remove the test gauge from the machine and reconnect the pipeline supply hose.



#### 7.16 Flowmeters

- (✓) 7.16.1 Oxygen Flowmeter
  - 7.16.1.1 Open the  $O_2$  cylinder valve.
  - 7.16.1.2 Is it possible to adjust the flow of oxygen to 10 L/min.? \_\_\_ (Y)
  - 7.16.1.3 Close the  $O_2$  cylinder valve and bleed the pressure.
  - 7.16.1.4 Connect the  $O_2$  pipeline supply, and verify the operation of the oxygen flowmeter.
  - 7.16.1.5 Is the correct flow control knob and label attached to the oxygen flow control valve? \_\_\_ (Y)
  - 7.16.1.6 Close the oxygen flow control valve.
- (✓) 7.16.2 Nitrous Oxide Flowmeter (if applicable)
  - 7.16.2.1 Set the oxygen flow to 4 L/min.
  - 7.16.2.2 Open the nitrous oxide cylinder valve.
  - 7.16.2.3 Is it possible to adjust the flow of nitrous oxide to 10 L/min.? \_\_\_\_\_(Y)
  - 7.16.2.4 Close the nitrous oxide cylinder valve and bleed the pressure.
  - 7.16.2.5 Connect the  $N_2O$  pipeline supply, and verify the proper operation of the  $N_2O$  flow.
  - 7.16.2.6 Is the correct flow control knob attached to the  $N_2O$  flow control valve? \_\_\_(Y)
  - 7.16.2.7 Close the oxygen and nitrous oxide flow control valves.

$(\checkmark)$	7.16.3 Air Flo	owmeter
	7.16.3.1	Connect the Air pipeline supply (if applicable).
	7.16.3.2	Is it possible to adjust the flow of air to 10 L/min.? $\_$ (Y)
	7.16.3.3	Close the air flow control valve and disconnect the Air pipeline supply.
	7.16.3.4	Is the correct flow control knob attached to the air flow control valve? $\underline{\hspace{1cm}}$ (Y)
$(\checkmark)$	7.16.4 Auxili	ary Oxygen Flowmeter (if applicable)
	7.16.4.1	Verify the auxiliary oxygen flowmeter flow control valve is closed.
	7.16.4.2	Connect a pressure manometer to the Aux O2 outlet.
	7.16.4.3	Is there an increase in pressure? $\underline{\hspace{1cm}}$ (N)
	7.16.4.4	Slowly open the Aux O2 flow control valve to apply a pressure of 50 cm $\rm H_2O$ to the manometer, then close control valve and start timer.
<b>(√</b> )	7.16.4.5	After 30 seconds, what is the pressure on the manometer?(40 - 50 cm $\rm H_2O)$
	7.16.4.6	Remove the manometer test fixture from the outlet.
	7.16.4.7	Is it possible to adjust the flow over the full range of the auxiliary oxygen flowmeter? $\underline{\hspace{1cm}}$ (Y)
	7.16.4.8	Set the flow rate to 5 L/min.
	7.16.4.9	Hold the calibrated oxygen sensor at the auxiliary oxygen flowmeter outlet.
<b>(✓</b> )	7.16.4.10	After the value stabilizes, what is the oxygen concentration? $\%$ (97-100)
	7.16.4.11	Remove the oxygen sensor from the auxiliary oxygen flowmeter, and insert it into the inspiratory valve dome adapter.
	7.16.4.12	Close the auxiliary oxygen flow control valve.

#### (✓) 7.17 Oxygen Monitor

- 7.17.1 Press the Man Spont key and press the rotary knob to confirm.
- 7.17.2 Verify the ventilator hose is connected to the breathing system.
- 7.17.3 Disconnect the oxygen sensor cable from the Oxygen Sensor interface.
- 7.17.4 The following message shall appear on the display: O2 Sensor Fail!.
- 7.17.5 Reconnect the oxygen sensor.
- **NOTE:** Make sure that the sensor has stabilized in ambient air for several minutes.
- 7.17.6 Press the Setup key, then perform O2 calibration per on-screen instructions.
- 7.17.7 After calibration is completed, verify the "O2 Sensor Fail" message disappears.
- 7.17.8 What is the oxygen concentration?  $_{--} \% (21)$
- 7.17.9 What is the low oxygen alarm default?  $\_$  % (20)
- 7.17.10 Press the key and select the OXYGEN LOW alarm limit. Does the low alarm limit illuminate? (Y)
- 7.17.11 Verify that the low alarm limit has a range from 18 to 99%. Adjust the alarm limit above current O2 monitor value.
- (✓) 7.17.12 INSP O2 LOW !!! shall appear on the display and the heading shall be flashing with a corresponding audible alarm.
  - 7.17.13 Place the oxygen sensor into the inspiratory valve dome adapter and set the APL valve to 70 and MAN position. Attach a 12-inch hose to the inspiratory port and occlude the bag mount.
  - 7.17.14 Set the oxygen flow to 4 L/min.
  - 7.17.15 Verify that the INSP O2 LOW !!! message has cleared.
  - 7.17.16 Select the OXYGEN HIGH alarm limit. Does the high alarm limit illuminate? \_\_\_ (Y)
  - 7.17.17 What is the high oxygen alarm default? \_\_\_ % (100)

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# **PMS PROCEDURE (continued)**

	7.17.18	Verify that the high alarm limit has a range from 100 to 19%.
	7.17.19	Set the high alarm limit to below the correct O2 reading.
<b>(✓)</b>	7.17.20	Does the message INSP O2 HIGH !! appear on the display? (Y)
	7.17.21	Return the high alarm limit to 100 and confirm.
	7.17.22	The INSP O2 HIGH message shall disappear.
<b>(</b> ✓ <b>)</b>	7.17.23	Within 3 minutes, what is the oxygen concentration? % (97-100)

#### 7.18 Oxygen Concentrations

**(✓**) 7.18.1 Oxygen + Nitrous Oxide Concentration (if applicable) 7.18.1.1 Verify the oxygen flow is at 4 L/min. 7.18.1.2 Depress the O<sub>2</sub> Flush button for 5 seconds. 7.18.1.3 Does the oxygen monitor read 97-100% after the value stabilizes?\_\_(Y) 7.18.1.4 Set the nitrous oxide flow to 2 L/min. **(✓)** 7.18.1.5 After the value stabilizes on the oxygen sensor, what is the  $O_2$ concentration? \_\_\_\_ % (62-72) 7.18.1.6 If measured value is within the range, close the N2O flow control valve and proceed to Section 7.18.2. **(✓)** 7.18.1.7 If measured value is not within range, close the nitrous oxide flow control valve and adjust the oxygen flow until total flow meter reads 4 L/min. What is the corresponding display flow rate? \_\_\_ L/min (3.9 - 4.7) **(✓)** 7.18.1.8 Set nitrous oxide flow to 2.5 L/min and oxygen flow to 2.5 L/min on the displays. What is the corresponding flow visually approximated on the total flow meter?  $\_\_L/min (4.5 - 5.5)$ 7.18.1.9 Close the nitrous oxide flow control valve. **(✓**) 7.18.2 Oxygen + Air Concentration 7.18.2.1 Depress the O<sub>2</sub>FLUSH button for 5 seconds. 7.18.2.2 Does the oxygen monitor read 97-100% after the value stabilizes?\_\_(Y) 7.18.2.3 Set the air flow to 2 L/min. **(✓)** 7.18.2.4 After the value stabilizes, what is the  $O_2$  concentration?  $_{--}\%(71-77)$ 7.18.2.5 Close the air and O2 flow control valves.

# 7.19 SORC

	7.19.1	Depress the $O_2$ FLUSH for 5 seconds.
	7.19.2	Set the O2 and N2O flow to 10 L/min.
	7.19.3	Set the O2 flow control valve to 0.8 L/min.
<b>(✓)</b>	7.19.4	What is the oxygen concentration after the value stabilizes? % $(\geq\!23\%)$
	7.19.5	Adjust the oxygen flow to 1.5 L/min.
<b>(✓)</b>	7.19.6	What is the oxygen concentration after the value stabilizes? % $(\geq\!23\%)$
	7.19.7	Adjust the oxygen flow to 2 L/min.
<b>(✓)</b>	7.19.8	What is the oxygen concentration after the value stabilizes? % $(\geq\!23\%)$
	7.19.9	Adjust the oxygen flow to achieve 10 L/min. N2O.
<b>(√</b> )	7.19.10	What is the oxygen concentration after the value stabilizes? % ( $\geq 23\%$ )
<b>(✓)</b>	7.19.11	Reduce the $\rm O_2$ flow to 0.5 L/min. Verify that the $\rm N_2O$ flow is greater than or equal to 0.6 L/min L/min.
	7.19.12	Reduce O2 flow to zero, then slowly increase O2 flow until N2O flow is present.
<b>(✓</b> )	7.19.13	What is O2 flow when N2O starts to flow (0.1 - 0.2 L/min.)
	7.19.14	Close the O2 and N2O flow control valves.

#### (✓) 7.20 Pressure Monitor

- 7.20.1 Verify unit is in Man Spont mode.
- 7.20.2 Disconnect the breathing pressure sensor line from the breathing system.
- 7.20.3 Connect a test pressure gauge and syringe to the breathing pressure sensor line.
- 7.20.4 Press the "Alarms" key.
- 7.20.5 What is the pressure apnea threshold default?  $\underline{\phantom{a}}$  cm  $H_2O(8)$
- 7.20.6 Verify that the pressure apnea threshold limit has a range from 5 to 30 cm  $\rm H_2O$ .
- 7.20.7 Adjust the threshold limit to 10 cm H2O.
- 7.20.8 Select the HIGH alarm limit, and confirm.
- 7.20.9 What is the high alarm limit default?  $\underline{\phantom{a}}$  cm  $H_2O$  (40)
- 7.20.10 Verify that the high alarm limit has a range from 10 to 70 cm  $H_2O$ .
- 7.20.11 Set the high alarm limit to 40 cm H<sub>2</sub>O, and confirm. Set the ventilator to Volume Control mode and confirm.
- 7.20.12 Increase the pressure to 25 cm  $\rm H_2O$ , then decrease the pressure to 0 cm  $\rm H_2O$  and start a stop watch.
- (✓) 7.20.13 What is the time when APNEA PRESSURE !! appears as a medium alarm tone with associated flashing yellow LED? \_\_\_\_ sec (26-34)
- (✓) 7.20.14 What is the time when the APNEA PRESSURE !!! appears as a high alarm with flashing red LED and corresponding audible alarms? \_\_\_\_ sec (56-64)
  - **NOTE:** For software version >1.20, with threshold low alarm enabled a corresponding threshold low alarm shall appear.
  - 7.20.15 After the APNEA PRESSURE !!! alarm is displayed as a high, slowly increase the test pressure.

# PMS PROCEDURE (continued)

<b>(√</b> )	7.20.16	At what pressure does the APNEA PRESSURE alarm deactivate? cm $\rm H_2O~(7\text{-}13)$
	7.20.17	Adjust the threshold to 18 cm $\rm H_2O.$
	7.20.18	Increase the pressure to 20 cm $\rm H_2O,$ maintain the pressure, and start a stopwatch.
<b>(✓</b> )	7.20.19	What is the time when CONTINUOUS PRESSURE appears as a high alarm? sec $(12\text{-}18)$
<b>(✓</b> )	7.20.20	Decreasing the pressure slowly, what is the pressure at which the CONTINUOUS PRESSURE alarm deactivates? cm $\rm H_2O~(15-21)$
	7.20.21	Increase the test pressure.
<b>(✓</b> )	7.20.22	At what pressure does the Airway Pressure High !!! alarm activate? cm $\rm H_2O~(38\text{-}42)$
	7.20.23	Bleed the pressure.
	7.20.24	Using a syringe in place of the squeeze bulb, slowly create a sub-atmospheric pressure.
<b>(√</b> )	7.20.25	At what pressure does the Pressure Negative !!! alarm activate? cm $\rm H_2O$ (-2 to -8)
	7.20.26	Return the pressure to zero.
	7.20.27	Does the PRESSURE NEGATIVE alarm deactivate? $\_\_(Y)$
	7.20.28	Using the syringe, increase the pressure to 20 cmH2O; then decrease the pressure to zero. $$
	7.20.29	Press the Autoset soft key.
	7.20.30	Does the threshold limit adjust to within four (4) cmH2O of peak pressure? (Y)
	7.20.31	Press the Man Spont key and confirm.
	7.20.32	Reconnect the breathing pressure sensor line to the breathing system.

#### 7.21 Ventilator

- (✓) 7.21.1 Manual Ventilation
  - 7.21.1.1 Cycle machine power-using On/Off switch and allow completion of the self-test.
  - 7.21.1.2 Verify the ventilator switches to standby mode after completion of self-test.
  - 7.21.1.3 Connect a test lung (8401892) to the breathing circuit Y-piece, and attach to breathing system.
  - 7.21.1.4 Attach a breathing bag to the breathing bag connector of the breathing system.
  - 7.21.1.5 Select Man Spont.
  - 7.21.1.6 Set the fresh gas flow to 3 L/min.
  - 7.21.1.7 Set the APL valve to MAN, 30 cmH2O.
  - 7.21.1.8 Verify that manual breathing is possible by manually squeezing the breathing bag. \_\_\_ (Y)
- (✓) 7.21.2 Spontaneous Breathing
  - 7.21.2.1 Set the APL valve to SPONT.
  - 7.21.2.2 Verify that spontaneous breathing is possible with the test lung. (Y)
  - 7.21.2.3 Close O2 flow control valve.
- (✓) 7.21.3 Flow Sensor Zeroing
  - 7.21.3.1 Select Standby mode and confirm.
  - 7.21.3.2 Disconnect the expiratory hose from the breathing system.
  - 7.21.3.3 Press the Calibrate Flow Sensor key and perform the on-screen instructions. At completion of calibration verify "Flow Calibration Completed" message appears.
  - 7.21.3.4 Reconnect the breathing circuit to the inspiratory and expiratory ports of the breathing system.

- (✓) 7.21.4 Ventilator Delivery
  - 7.21.4.1 Set APL to Man position and set to 30 cmH2O.
  - 7.21.4.2 Switch to Volume Control mode and set the fresh gas flow to 3 L/min.
  - 7.21.4.3 Interconnect a test volumeter (P/N 2212300 w/4115087 connectors) between the expiratory limb of breathing system and breathing circuit.
  - 7.21.4.4 Is Volume Mode displayed and flashing? \_\_\_\_(Y)
  - 7.21.4.5 Depress Flush momentarily to inflate bag.
  - $7.21.4.6 \quad Set: pmax = 70 \; mbar \; (cmH2O)$   $Vt = 380 \; mL$   $Freq = 12 \; BPM$  TI:TE = 1:1 TIP:TI = 10%  $PEEP = 0 \; cmH2O$
  - 7.21.4.7 Press the rotary knob.
  - 7.21.4.8 Is Volume Control displayed? \_\_\_(Y)
  - 7.21.4.9 Verify that ventilation starts. \_\_\_(Y)
  - 7.21.4.10 Does drive run quietly and smoothly (Y)?
- ( $\checkmark$ ) 7.21.4.11 Verify display Vte = 300 450 mL (\_\_\_ mL/min.)
- (✓) 7.21.4.12 Verify Minute Volume on test volumeter and MV on display are within 20% of each other.
  - 7.21.5 PEEP Pressure Accuracy
    - 7.21.5.1 After 10 breaths, press PEEP parameter button.
- (✓) 7.21.5.2 Verify displayed values for the following PEEP settings:

Setting	Displayed Value
0	0 + 2 cmH2O
10	$10 \pm 2$ cmH2O or 20% of setting, which ever is greater
15	$15 \pm 2$ cmH2O or 20% of setting, which ever is greater

7.21.5.3 Return PEEP setting to Zero and confirm.

**(** 

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#### 7.21.6 Pmax Accuracy

- 7.21.6.1 Connect a test pressure gauge in line with the pressure port connector of breathing system.
- 7.21.6.2 Remove test lung and seal off Y-piece.
- $(\checkmark)$  7.21.6.3 Verify test gauge display and breathing gauge values for the following Pmax settings:

Setting	Test Gauge Value
25	25 ± 5 cmH2O
40	40 ± 5 cmH2O
60	60 ± 5 cmH2O
70	70 ± 5 cmH2O

#### 7.21.7 APL Valve Man/Spont

7.21.7.1 Set ventilator to Man Spont

Lever APL Valve		Rotary Knob APL Valve	
7.21.7.2	Set O2 and Air Fresh Gas flows to 10L/min ea. (20 L/min. total)		
7.21.7.3	Set APL valve to MAN, 30 cmH2O.	Set APL Valve to 40 cm H2O	
7.21.7.4	Verify pressure is 27 - 33 mbar (cmH2O) as shown on digital manometer.	Verify pressure is 34 - 46 mbar (cmH2O) as shown on digital manometer.	
7.21.7.5	Set APL valve to SPONT.		
7.21.7.6	Verify pressure display is 0 - 3 mbar (cmH2O).		

7.21.7.7 Set fresh gas flow to zero.

7.21.7.8 Reconnect test lung to breathing circuit and remove the test pressure gauge from the breathing system.

#### 7.21.8 Pressure Limiting Valve Test

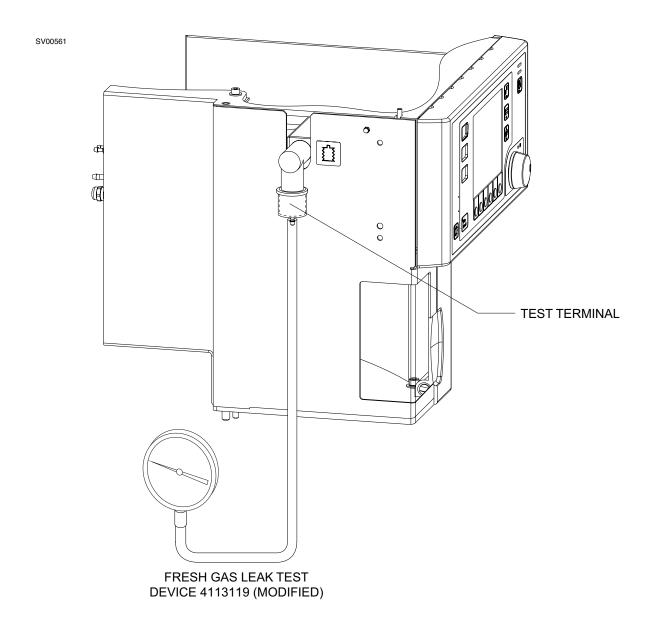
7.21.8.1 Set ventilator to Volume Control mode and confirm.

# PMS PROCEDURE (continued)

**FABIUS GS** 

7.21.8.2 Set: pmax = 40 mbar (cmH2O) Vt = 600 mL Freq = 6 BPM
TI:TE = 1:1
TIP:TI = 10%
PEEP = 0 mbar (cmH2O)
Remove ventilator hose from ventilator and connect a digital

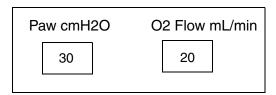
7.21.9 manometer to the ventilator outlet port. (✓) 7.21.10 Verify relief valve opens between 70 and 80 mbar (cmH2O) when ventilator is in inspiratory phase.



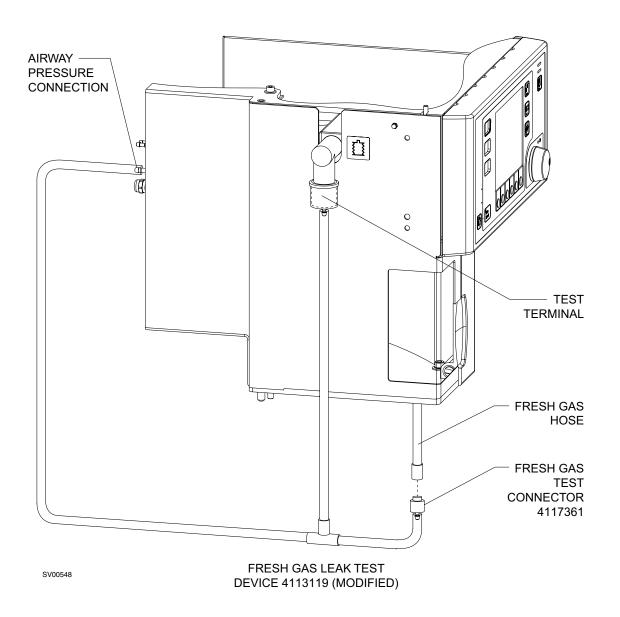
- 7.21.11 Auxiliary Air Valve Test
- (✓) 7.21.11.1 Close all flow control valves. Verify vacuum valve opens at the pressure indicated in the following table, when ventilator is in expiratory phase.

	Software Version	-3 mbar neg relief valve	-8 mbar neg relief valve
US	1.20	-2.5 to -6.0 mbar	N/A
	>1.3x	N/A	-7.0 to -8.0 mbar
non-US	1.20	-2.5 to -6.0 mbar	N/A
	>1.2x	N/A	-7.0 to -8.0 mbar

- 7.21.12 Piston Chamber Leak Test
  - **NOTE:** For software version  $\leq 1.20$ , proceed to the next step. For software version  $\geq 1.3x$ , skip to Part (b) of Step 7.21.12.5
  - 7.21.12.1 Select Standby mode.
  - 7.21.12.2 Connect test setup as shown in the illustration on the next page.
  - 7.21.12.3 Press the Run Leak Test softkey.
  - **NOTE:** Do not run the leak test per on-screen instructions. Continue with piston chamber leak test as follows.
  - 7.21.12.4 Use the O2 flow control valve to set a stable pressure of 30 cmH2O as shown on the display:



- (✓) 7.21.12.5 (a) Verify leakage rate is <20 mL/min. as shown on display.
  - (b) For software version 1.3x, perform the Leak/Compl Test and verify ventilator leak test indicates a Pass condition.
  - 7.21.12.6 Remove test setups and reconnect ventilator hose to ventilator port.



#### 7.21.13 Vacuum Pressure

- 7.21.13.1 Set Fabius GS to Volume mode.
- 7.21.13.2 Remove APL bypass hose from breathing system and attach to digital manometer.
- (✓) 7.21.13.3 Verify vacuum is between -150 and -240 cmH2O (mbar) (-110 and -175 mmHg) as shown on digital manometer. \_\_\_ cmH2O
  - 7.21.13.4 Disconnect APL bypass hose from digital manometer and reconnect to APL port on breathing system.

### 7.22 Volume Alarms

	7.22.1	Set ventilator to Volume Control mode and confirm.
	7.22.2	Set: pmax = 40 mbar (cmH2O)     Vt = 380 mL     Freq = 12 BPM     TI:TE = 1:1     TIP:TI = 10%     PEEP = 0 mbar (cmH2O)
	7.22.3	Press the Alarms key, scroll to MV High Alarm and confirm. Does a box appear around the Minute Volume High Alarm Limit?(Y)
	7.22.4	What is the High Minute Volume Alarm default? $\_\_$ (12) Press to confirm.
	7.22.5	Scroll to Minute Volume Low Alarm and confirm. What is the minute Volume Low default? $(3.0)$
<b>(√</b> )	7.22.6	Adjust the low minute volume alarm to 5.0 liters and confirm. Does the MINUTE VOLUME LOW $!!$ alarm appear as a mid alarm with a corresponding yellow LED? $\_$ $(Y)$ .
	7.22.7	Adjust minute volume alarm to 2.0 and confirm. Does the Minute Volume Low alarm disappear? $\underline{\hspace{1cm}}$ (Y).
	7.22.8	Disconnect breathing hose from expiratory connection and start a stop watch.
<b>(✓)</b>	7.22.9	What is the time when APNEA FLOW !! appears as a mid alarm? sec $(13$ - $17)$
<b>(✓)</b>	7.22.10	What is the time when APNEA FLOW !!! appears as a high alarm? $\_\_$ sec (26 - 34)
	7.22.11	Disconnect the respiratory volume sensor cord from the Flow sensor.
<b>(✓)</b>	7.22.12	Does the "FLOW SENSOR FAIL !" message appear as an Advisory with a single audible tone? $\underline{\hspace{1cm}}$ (Y)
	7.22.13	Does the APNEA FLOW !!! alarm disappear? (Y)
	7.22.14	Do the numerical values associated with volume disappear? $\underline{\hspace{1cm}}$ (Y)
	7.22.15	Reconnect the respiratory volume sensor cord to the flow sensor, and expiratory limb of breathing circuit to breathing system.
	7.22.16	Press Standby, confirm, and recalibrate the flow sensor.

#### 7.22.17 Fresh Gas Low

- 7.22.17.1 Select Volume Control mode and confirm.
- 7.22.17.2 Disconnect the hose attached to the breathing system's inspiratory port.
- (\*) 7.22.17.3 After 30 seconds verify the APNEA PRESSURE !!!, APNEA FLOW !!!, MINUTE VOLUME LOW !!! and FRESH GAS LOW !! alarm messages appear on the display with a corresponding audible alarm.
  - 7.22.17.4 Reconnect the patient Y connector to the patient inspiratory port and activate the flush.
  - 7.22.17.5 Verify the FRESH GAS LOW!! alarm disappears after two (2) seconds following the next ventilator cycle. \_\_\_\_ (Y)
  - 7.22.17.6 For software version 1.3n, with No Fresh Gas enabled, verify a No Fresh Gas !!! alarm appears.

#### (✓) 7.23 Audio Silence

- 7.23.1 Press the key.
- 7.23.2 Does the LED on the Silence Alarms key light? Is the audio alarm silenced for 120 sec.?
- 7.23.3 Press Standby key and confirm.
- 7.23.4 Cycle the system power and wait for the Standby screen to appear.
- 7.23.5 Press Volume Control and confirm.
- 7.23.6 Verify the 120-sec. delay starts at power-up.
- 7.23.7 Disconnect all test equipment.

#### (✓) 7.24 Oxygen Flush Valve

- 7.24.1 Press and release the O<sub>2</sub>FLUSH button.
- 7.24.2 Does the flow of oxygen stop immediately? \_\_ (Y)
- 7.24.3 Connect a 12-inch hose to the inspiratory valve.
- 7.24.4 Occlude the bag mount with test plug.
- 7.24.5 Insert the sensor from a calibrated  $O_2$  Med into the valve dome adapter on the inspiratory valve.
- 7.24.6 Close all flow control valves.
- 7.24.7 Press the O<sub>2</sub>FLUSH button.
- ( $\checkmark$ ) 7.24.8 What is the O<sub>2</sub> concentration after the value stabilizes?\_\_\_%O<sub>2</sub> (97-100)
  - 7.24.9 Remove the  $O_2$  sensor from the inspiratory dome and install the plug.
  - 7.24.10 Disconnect the fresh gas hose from the breathing system. Using the fresh gas test connector (4117361), test terminal (4104389), and appropriate adapter (4115087), connect to fresh gas hose and attach test terminal to in port of test volumeter.
  - 7.24.11 Press and hold the  $O_2$  FLUSH button for 15 seconds; multiply the value by 4.

PMS PROCEDURE (continued)

(✓) 7.24.12 What is the oxygen flush flow rate? \_\_\_L/min.

Minimum: 35 L/min. @ 50 psi (domestic) Minimum: 25 L/min. @ 40 psi (2.8 bar) Maximum: 75 L/min. @ 87 psi (6.0 bar)

- 7.24.13 Remove the test minute volumeter and test fixture, and reconnect the fresh gas hose.
- 7.24.14 Turn the System Power switch to ON.

#### 7.25 Final Tests

- (✓) 7.25.1 Operator's Instruction Manual
  - 7.25.1.1 Verify that the availability/location of the machine's Operator's Instruction Manual is in close proximity of the machine.
- (**✓**) 7.25.2 Lamp Test
  - 7.25.2.1 Verify that the table lamp is working properly.
- (**✓**) 7.25.3 Final Check
  - 7.25.3.1 Verify that all cylinder pressure gauges indicate zero (if applicable).
  - 7.25.3.2 Verify that the pipeline hoses are connected to the hospital pipeline.
  - 7.25.3.3 Verify that the APL valve knob is fully open.
  - 7.25.3.4 Verify that the  $O_2$  sensor is removed from the valve dome and the plug is inserted in the inspiratory valve dome.
  - 7.25.3.5 Verify that the machine is plugged into a live outlet.
  - 7.25.3.6 Verify all test equipment is removed from machine.
  - 7.25.3.7 Return all machine controls and settings to their original state.

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